Currently Active ILD Studies and Studies due to start 2021/early 2022

GALACTIC
A Phase 2 randomised double-blind controlled study comparing the experimental inhaled antifibrotic drug GB0139 to placebo.

GB0139 is an inhaled galectin-3 (Gal-3) inhibitor. Gal-3 is thought to act as a pro fibrotic mediator by modulating the activity of fibroblasts and macrophages in chronically injured tissues

Inclusion Criteria

1. ILD specialist MDT diagnosis of IPF within the last 5 years.
2. FVC > 45% predicted, TLCO 30-79% predicted
3. NOT currently taking nintedanib or pirfenidone

Exclusion Criteria (key points)

1. FEV1/FVC <0.7

Primary outcome.

1. Change in FVC (ml) at 52 weeks

Study Activity

1. Randomised to study drug or placebo for 12 months of treatment
2. 8 visits to research centre at Southampton with lung function and blood tests.

Studies due to start later this year

CANAL-TR12 – provisional start date Oct/Nov 2021
A Phase 2 double-blind randomised controlled two-period cross-over designed study of Nalbuphine extended release (ER) tablets for treatment of cough in IPF.

Nalbuphine is a synthetic opiate (dual actions; kappa agonist - mu receptor antagonist) and has been licensed for treatment of pain for over 20 years in its injectable form. Reformulated in an ER tablet it is being trialled as a treatment for IPF cough.

Inclusion Criteria

1. Diagnosis of definite or probable IPF
2. FVC>40% and TLCO>25% predicted
3. Cough > 8 weeks with ≥4/10 severity

Exclusion Criteria (key points)

1. Long-term oxygen therapy >16 hours/day
2. Taking opiates/benzodiazepines or serotonergic medications for duration of study.

Primary Outcome

1. Effect of study drug on mean daytime cough frequency.

Study Activity

1. Two 3-week treatment cycles blinded to either study drug or placebo
2. Participants wear 24-hour cough monitor at start and end of each treatment cycle
3. Total of 10 visits over 4-6 months including lung function and bloods

TIPAL – provisional start date December 2021/January 2021
A randomised placebo-controlled study of lansoprazole in IPF

Although many patients with IPF take lansoprazole (or similar medications) its effectiveness as a treatment of IPF has not yet been proven in a definitive research study. Although generally safe medications, meta-analysis has identified that patients taking PPIs maybe at increased risk of pneumonia. Hence robust research evidence for their use in IPF is required. The TIPAL study aims to answer this research question.

Inclusion Criteria

1. Diagnosis of IPF from local or specialist centre
2. Sub-study for patients with chronic cough

Exclusion Criteria

1. Long-term oxygen therapy >16 hours/day
2. Patients diagnosed with Zollinger-Ellison syndrome, Barrett's oesophagus, previous oesophagectomy, previous GI bleed on long-term NSAIDS/anticoagulation.

Primary Outcome

1. Change in FVC% predicted at 12 months

Study Activity

1. Randomisation to 1 year of lansoprazole or placebo
2. Weekly home spirometry testing
3. 4 visits to research centre at Southampton over 1-year period for lung function and questionnaires.
4. 24-hour cough monitor at baseline and 3 months for those in cough sub-study

PATHOLOGICAL MECHANISMS OF PULMONARY FIBROSIS start Dec 2021/Jan 2022

Laboratory based study researching into the cellular causes of pulmonary fibrosis

Inclusion criteria: Patients with ILD of any cause undergoing bronchoscopy with bronchoalveolar lavage (BAL) as part of standard clinical care at University Hospital Southampton.

Study Activity: a small additional BAL sample will be taken for research investigating into the causes of pulmonary fibrosis.

TRIALS COMING TO SOUTHAMPTON SOON
The research team are currently in negotiation with pharmaceutical companies over participation in at least 4 additional trials in Pulmonary Fibrosis, and we will keep everyone updated as more details emerge.

For more info please email ILDresearch@uhs.nhs.uk or tim.wallis@uhs.nhs.uk